

REMARKS

Claims 1-22 and 75-94 are pending in the instant application.

Process claims 23-44 were previously withdrawn from consideration, Applicants reserve the right to rejoin the withdrawn process claims upon the allowance of one or more of the product claims from which they depend (MPEP §821.04).

Claim 22 has been amended without prejudice or disclaimer. Support for the amendment can be found at least, for example, at page 6, lines 9-11 of the specification. No new matter has been added.

I. Specification/Compliance with Sequence Rules

The Examiner has objected to the specification for failing to comply with the sequence disclosure requirements of 37 CFR 1.821 and 1.825. Specifically, the Examiner notes that the sequence TCTCTGGTTAGACCAGATCTG, identified as SEQ ID NO:12 at page 31, line 9 of the specification, is missing from the sequence listing. Moreover, the Examiner notes that the sequence identifier at page 31, line 8 of the specification is erroneously duplicated at page 31, line 9. Accordingly, the specification has been amended herewith to renumber the sequence at page 31, line 9 as **SEQ ID NO: 21**. In addition, a substitute sequence listing is submitted herewith which includes SEQ ID NO: 21.

II. Claim Rejections -35 USC §112

Claim 22 has been rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the specification as filed fails to disclose an example of a protein that can associate with an siRNA complementary to an HIV genome, wherein the protein recognizes the portion of the HIV genome to which the siRNA is complementary. However, the Examiner appears to acknowledge that support for “a complex of siRNA and proteins that recognize and degrade RNAs with a sequence sufficiently homologous to that of the siRNA” can be found at page 6, lines 9-11 of the specification. Accordingly, without acquiescing to the rejection and solely in the interest of expediting the allowance of the application, Applicants have amended claim 22 to conform to the written support indicated by the Examiner (see page 4 of 2/15/07 Office Action).

III. Claim Rejections -35 USC §102

a. *Rejection of Claims 1-22 and 75-93 under 35 U.S.C. § 102(a) and §102(e) in view of Lois-Cabelle (US 20030059944)*

The Examiner has rejected claims 1-22 and 75-93 under 35 U.S.C. § 102(a) and § 102(e) as allegedly being anticipated by Lois-Cabelle *et. al.* (US 20030059944A1). Specifically, the Examiner cites passages of the Lois-Cabelle *et al.* patent publication (e.g., paragraphs 142, 152, and 159) as allegedly teaching “methods and compositions for producing siRNAs from retroviral vectors, including shRNAs directed against any region of about 19-25 nucleotides in length of the 9-kb transcript of the integrated HIV virus”.

Applicants traverse the rejection.

As an initial matter, Applicants respectfully submit that the publication date (March 27, 2003) of Lois-Cabelle *et al.* falls after both the September 22, 2002 filing date of US Provisional Application 60/428,631 and the February 4, 2003 filing date of US Provisional Application 60/444,893. Not only does the instant application properly claim priority under §119(e) to both priority applications, but Applicants respectfully submit that the pending claims are fully supported by their content. Accordingly, for at least these reasons, Lois-Cabelle *et al.* is not available for use by the Examiner as a reference, either basic or auxiliary, in the rejection of the claims of the present application under 35 U.S.C. §102(a).

Notwithstanding the above, Applicants submit herewith a Declaration under 37 C.F.R. §1.131 (herein, “Declaration”) by Drs. Mario Stevenson and Jean-Marc Jacque, co-inventors of the instant application. It is the Applicant’s position that the Declaration obviates the Examiner’s rejection based on Lois-Cabelle *et al.* As described in the Declaration (filed herewith), Applicants’ invention was completed prior to the publication date (March 27, 2003) of Lois-Cabelle *et al.* Applicants submit that the data referenced in the Declaration is also reproduced in the working examples set forth in the specifications of the instant application and both priority documents (US Provisional Applications 60/428,631 and 60/444,893). Accordingly, for at least these additional reasons, Lois-Cabelle *et al.* is not available for use by the Examiner as a reference, either basic or auxiliary, in the rejection of the claims of the present application under 35 U.S.C. §102(a). Therefore, it is clear that the above-quoted rejection of claims 1-22 and 75-

93 under 35 U.S.C. §102(a) in view of *Lois-Cabelle et al.* should be reconsidered and withdrawn.

In addition, the Declaration establishes that Applicants' invention was completed prior to the filing date (September 13, 2002) and both the June 18, 2002 (60/322,031) and August 27, 2002 (60/347,782) priority dates of *Lois-Cabelle et al.* The passages of *Lois-Cabelle et al.* publication cited by the Examiner are not found in either the 60/322,031 (September 13, 2001) or 60/347,782 (January 9, 2002) priority applications of *Lois-Cabelle et al.* Indeed, it is clear that neither of the September 13, 2001 or January 9, 2002 priority applications teaches or suggests a small interfering RNA (siRNA) comprising a sequence sufficiently complementary to a portion of an HIV genome to mediate RNAi of the HIV genome portion. Therefore, the rejection of claims 1-22 and 75-93 under 35 U.S.C. §102(e) in view of *Lois-Cabelle et al.* should be reconsidered and withdrawn.

For the avoidance of any doubt, Applicants respectfully submit that the Declaration is properly admissible to remove *Lois-Cabelle et al.* as a prior art reference under 35 U.S.C. §102(e), since *Lois-Cabelle et al.* **does not claim the same patentable invention** as the Applicants (see MPEP 715 (I)). Moreover, as stated in MPEP 2305 (I): "...the claims that matter for the purposes of 37 CFR 1.131 are not the published claims but the currently existing claims. For example, if the claims that were published in a published application have been significantly modified during subsequent examination, they may no longer interfere with the rejected claims." Accordingly, since the pending claims do not conflict with the currently pending claims of *Lois-Cabelle et al.*¹, Applicants submit that the Declaration should be entered and the reference should be removed from consideration.

b. Rejection of Claims 1-3, 7-19, 22, 75, 76, 79, 80, and 83-94 under 35 U.S.C. § 102 (e) in view of Engelke (US 20030148519A1)

The Examiner has rejected claims 1-3, 7-19, 22, 75, 76, 79, 80, and 83-94 under 35 U.S.C. § 102(e) as allegedly being anticipated by *Engelke et al.* (US 20030148519A1). Specifically, the Examiner cites passages of the *Engelke et al.* patent publication (e.g.,

¹ The Examiner is directed to the claim amendments filed in US Application 10/243,553 on December 7, 2006.

paragraphs 158, 245, and 282-284) as allegedly teaching “methods and compositions for vector-driven intracellular expression and delivery of siRNAs of about 18-25 base pairs” and “inhibition of HIV pol”.

Applicants traverse the rejection.

The enclosed Declaration establishes that Applicants' invention was completed in this country prior to the filing date (November 14, 2002) of Engelke *et al.* The passages of the Engelke *et al.* publication cited by the Examiner are not found in the November 14, 2001 (60/332,170) priority application of Engelke *et al.* Indeed nothing in the priority application of Engelke *et al.* teaches or suggests a small interfering RNA (siRNA) comprising a sequence sufficiently complementary to a portion of an HIV genome to mediate RNAi of the HIV genome portion. Therefore, the rejection of claims 1-3, 7-19, 22, 75, 76, 79, 80, and 83-94 under 35 U.S.C. §102(e) in view of Engelke *et al.* should be reconsidered and withdrawn.

Applicants respectfully submit that the Declaration is properly admissible to remove Engelke *et al.* as a prior art reference under 35 U.S.C. §102(e), since the currently pending claims of Engelke *et al.* and the instant application ***are not directed to the same patentable invention.*** Accordingly, since the pending claims do not conflict with the currently pending claims of Engelke *et al.*,² Applicants submit that the Declaration should be entered and the reference should be removed from consideration.

c. Rejection of Claims 1-11, 14-22, 75-84, and 86-94 under 35 U.S.C. § 102 (e) in view of McSwiggen (US 20030175950A1)

The Examiner has rejected claims 1-11, 14-22, 75-84, and 86-94 under 35 U.S.C. § 102(e) as allegedly being anticipated by McSwiggen (US 20030175950A1). Specifically, the Examiner cites passages of the McSwiggen *et al.* patent publication (*e.g.*, paragraphs 12, 13, 23, 67, and 110) as allegedly teaching “RNA interference mediated inhibition of HIV gene expression using short interfering RNA”.

² The Examiner is directed to the claim amendments filed in US Application 10/294,957 on February 5, 2007.

Applicants traverse the rejection.

The enclosed Declaration establishes that Applicants' invention was completed prior to the filing date (August 21, 2002) and both the May 29, 2002 and July 23, 2002 priority dates listed on the McSwiggen *et al* publication. Moreover, the passages of the McSwiggen *et al* publication cited by the Examiner are not found in the May 29, 2001 (60/294,140) priority application of McSwiggen *et al*. Indeed, nothing in the May 29, 2001 priority application teaches or suggests a small interfering RNA (siRNA) comprising a sequence sufficiently complementary to a portion of an HIV genome to mediate RNAi of the HIV genome portion. Therefore, the rejection of claims 1-11, 14-22, 75-84, and 86-94 under 35 U.S.C. §102(e) in view of McSwiggen *et al*. should be reconsidered and withdrawn.

Applicants respectfully submit that the Declaration is properly admissible to remove McSwiggen *et al* as a prior art reference under 35 U.S.C. §102(e), since the pending claims of McSwiggen *et al*.³, ***are not directed to the same patentable invention*** claimed by Applicants. Should the Examiner consider the claims to conflict, Applicants respectfully submit that the Declaration should be nevertheless be entered and considered as provided by MPEP 2305 (I), which states:

"Similarly, if a published application contains claims to the same invention, but the claims in the published application are not in condition for allowance, then no interference is yet possible. 37 CFR 41.102. Since the claims in the published application might never be allowed in their present form, it is not appropriate to proceed as though an interference might be inevitable. Consequently, an affidavit under 37 CFR 1.131 may be submitted."

Accordingly, since the pending claims of McSwiggen *et al*. are not in condition for allowance⁴, Applicants submit that the Declaration should be entered and the reference removed from consideration.

³ The Examiner is directed to the claim amendments filed in US Application 10/225,023 on February 28, 2007.

⁴ The Examiner is directed to the Non-Final Rejection mailed on May 16, 2007.

SUMMARY

In view of the above amendment and response, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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